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**PATENT COOPERATION TREATY  
PCT  
INTERNATIONAL PRELIMINARY EXAMINATION REPORT**

REC'D 26 APR 2005

PCT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 12389950/KBM/KXG	<b>FOR FURTHER ACTION</b>	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416).
International Application No.  PCT/AU2003/001724	International Filing Date (day/month/year)  24 December 2003	Priority Date (day/month/year)  24 December 2002
International Patent Classification (IPC) or national classification and IPC  Int. Cl. <sup>7</sup> C07K 7/08; A61K 38/10; A61P 29/00, 35/00, 37/00; G01N 33/53.		
Applicant  WALTER AND ELIZA HALL INSTITUTE OF MEDICAL RESEARCH et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 6 sheets, including this cover sheet.

This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of sheet(s).

3. This report contains indications relating to the following items:

- I  Basis of the report
- II  Priority
- III  Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV  Lack of unity of invention
- V  Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI  Certain documents cited
- VII  Certain defects in the international application
- VIII  Certain observations on the international application

Date of submission of the demand 25 June 2004	Date of completion of the report 8 April 2005
Name and mailing address of the IPEA/AU  AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaaustralia.gov.au Facsimile No. (02) 6285 3929	Authorized Officer  <b>MARIE-ANNE FAM</b> Telephone No. (02) 6283 2254

**I. Basis of the report**

## 1. With regard to the elements of the international application:\*

- the international application as originally filed.
- the description, pages , as originally filed,  
pages , filed with the demand,  
pages , received on with the letter of  
pages , as originally filed,
- the claims, pages , as amended (together with any statement) under Article 19,  
pages , filed with the demand,  
pages , received on with the letter of  
pages , as originally filed,
- the drawings, pages , filed with the demand,  
pages , received on with the letter of  
pages , as originally filed,  
pages , filed with the demand,  
pages , received on with the letter of  
 the sequence listing part of the description:  
pages , as originally filed  
pages , filed with the demand  
pages , received on with the letter of

## 2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language which is:

- the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- the language of publication of the international application (under Rule 48.3(b)).
- the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

## 3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- contained in the international application in written form.
- filed together with the international application in computer readable form.
- furnished subsequently to this Authority in written form.
- furnished subsequently to this Authority in computer readable form.
- The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

4.  The amendments have resulted in the cancellation of:

- the description, pages
- the claims, Nos.
- the drawings, sheets/fig.

5.  This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).\*\*

\* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

\*\* Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.  
PCT/AU2003/001724**III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be nonobvious), or to be industrially applicable have not been examined in respect of:

- the entire international application,  
 claims Nos: 1-41 and 44-48 (in part)

because:

- the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (*specify*):

- the description, claims or drawings (*indicate particular elements below*) or said claims Nos. 1-41 and 44-48 (in part) are so unclear that no meaningful opinion could be formed (*specify*):

A complete search of the claims was not possible for economic reasons. Consequently this written opinion is based only on constrained peptide sequences in so far as covered by the search.

- the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.  
 no international search report has been established for said claim Nos.

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

- the written form has not been furnished or does not comply with the standard.  
 the computer readable form has not been furnished or does not comply with the standard.

**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement****1. Statement**

Novelty (N)	Claims 1-41, 44-48	YES
	Claims 42, 43	NO
Inventive step (IS)	Claims 1-41, 44-48	YES
	Claims 42, 43	NO
Industrial applicability (IA)	Claims 1-48	YES
	Claims -	NO

**2. Citations and explanations (Rule 70.7)****Novelty and Inventive Step**

The following documents were identified in the search report:

- D1 WO 2000/059526
- D2 WO 2002/020568
- D3 WO 2002/072761

The present claims 42 and 43 define an assay for identifying compounds that bind to a member of the Bcl-2 family of proteins. The procedure involves the use of a peptide that binds a Bcl-2 family protein and comprises the amino acid sequence IAQELRRIGDEFN.

D1 discloses the peptide Sequence Id. No. 46, which comprises the amino acid sequence defined by the present claim 42. Sequence Id. No. 46 binds to various members of the Bcl-2 class of proteins and may be used in competition binding assays in order to identify further compounds that bind to Bcl-2. Consequently claims 42 and 43 are not novel or inventive in view of D1.

Similarly D3 describes peptide Sequence Id. No. 1, which comprises the amino acid sequence of the present claim 42, and the use of this substance in Bcl-2 competitive binding assays. Hence claims 42 and 43 also lack novelty and are not inventive in light of this document.

D2 also describes methods for identifying compounds that bind to a member of the Bcl-2 family of proteins. The peptide sequences used in these assays bind to Bcl-2, but differ from the amino acid sequence defined by the present claim 42. However it would be a routine matter for the skilled addressee to substitute one peptide sequence that binds to Bcl-2 with another sequence that also has this property, in order to perform a Bcl-2 competitive binding assay. Thus claims 42 and 43 are not inventive in view of D2.

None of D1-D3 discloses constrained peptide sequences as defined by the present formula (I) or the medical use of these substances. Consequently claims 1-41 and 44-48 are novel and inventive.

(see also Supplemental Box)

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**VIII. Certain observations on the international application**

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

1. Claims 1, 41 and 44-48 are not fully supported by the description. The amino acid sequence (I) defined by these claims includes within its scope an enormous number of possible compounds, however the specification only provides support for certain conformationally constrained peptide sequences.

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**Supplemental Box**

(To be used when the space in any of the preceding boxes is not sufficient)

**Continuation of Box V**

**Industrial Applicability**

Claims 1-48 meet the requirements for industrial applicability.